



International Alliance for  
Biological Standardization

**Maintaining the Quality of Vaccines through the Use of Standards:  
Current Challenges and Future Opportunities  
Library and Archives Canada, Ottawa, Canada  
June 21-22, 2023  
Abstract**

**Emmanuelle Coppens, Sylvie Uhlich**

Sanofi Vaccines, Marcy l'Etoile, France

**Title: Experience on the implementation and the use of reference standards for human vaccines potency testing**

As an introduction, general practices at Sanofi Vaccines for the choice and qualification of reference standards will be described as well as their stability monitoring. A focus will be made on qualification study design in the frame of the replacement of a reference standard.

Two case studies on Tetanus *in vivo* potency and Polio D antigen assays, where a change to a new IRS (International Reference Standard) showed an impact on product consistency with risk of out of specification results, will be shared. For each case, a similar root cause was identified related to the methodology for assigning the titer of the IRS. A common remediation plan based on the implementation of an in-house reference will be presented.

General recommendations on the establishment of IRS will be made. The respective use of an IRS or in-house reference standard will be discussed.

This work was funded by Sanofi.

Emmanuelle Coppens and Sylvie Uhlich are Sanofi employees and may hold shares and/or stock options in the company.